APR 2 3 2010

Attachment B. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: **k093940**

1. Submitter's Identification:
   TaiDoc Technology Corporation
   6F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

   Correspondence:
   Debra Liang
   Regulatory Affairs Specialist
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   Email: debra.liang@taidoc.com.tw

   Date of submission: December 21, 2009

2. Device name:
   Proprietary name: **ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System**

   Regulatory information:
   A. Regulation section: 21 CFR § 862.1345, Glucose Test System

   B. Classification: Class II (Glucose Test System)

   C. Product Code: NBW, System, Test, Blood Glucose, Over The Counter
   CGA, Glucose Oxidase, Glucose

   D. Panel: 75, Clinical Chemistry – Glucose Test System

3. Intended Use:

ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System, Model TD-4276, is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm, forearm, upper-arm, calf and thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. The alternative site testing in the system can be used only during steady-state blood glucose conditions.

The device is not to be used for the diagnosis or screening of diabetes or tested on neonates.

4. Device Description:

The kit of ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System consist of four main products: the meter with blood glucose measurement function, test strips, control solution (cleared under k041107), and a lancing device. These products have been designed and tested to work together as a system to produce accurate blood glucose test results.

5. Substantial Equivalence Information:

A. Predicate device name:

ADVOCATE REDI-CODE BLOOD GLUCOSE MONITORING SYSTEM, MODEL TD-4223F

Predicate K number: K072039

B. Comparison with predicate:

The modified ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- packaged using the same materials, and

- Manufactured by the same process.

The modifications encompass:

- Software modification
- Removal of ketone warning message
- Physical appearance change
- Engineering change
- Memory capacity change
- Removal of data transmission function
- Labeling change due to the above modifications

6. Test Principle:
   For blood glucose, the detection and measurement is by an electrochemical biosensor technology using glucose oxidase.

7. Performance Characteristics:
   The ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

   Software verification and validation testing confirmed that the performance, safety and effectiveness of the ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System is equivalent to the predicate device.

8. Conclusion:
   Based on the information provided in this submission, the ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System is substantially equivalent to the predicate ADVOCATE REDI-CODE BLOOD GLUCOSE MONITORING SYSTEM, MODEL TD-4223F.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

TaiDoc Technology Corporation
c/o Debra Liang
Regulatory Affairs Specialist
6F, No.127, Wugong 2nd Rd., Wugu Township
Taipei County, China (Taiwan) 248

APR 2 3 2010

Re: k093940
Trade/Device Name: ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System, Model TD-4276
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: April 12, 2010
Received: April 14, 2010

Dear Ms. Liang

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 8 Indications for Use

Indications for Use

510(k) Number: K093940

Device Name: **ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System, Model TD-4276**

Indications for Use:

ADVOCATE REDI-CODE DASH Blood Glucose Monitoring System, Model TD-4276, is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm, forearm, upper-arm, calf and thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. The alternative site testing in the system can be used only during steady-state blood glucose conditions.

The device is not to be used for the diagnosis or screening of diabetes or tested on neonates.

Prescription Use ___X___ And/Or Over the Counter Use ___X___.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K093940